

EXHIBIT F

	Hits	Gigabytes
(*90483* OR *90866* OR *78020*)	2,887	8.56
(EIR OR "establishment inspection report") AND <facility name> AND (<Drug Name> OR (<Solvents> AND NOT <other drug names>))	26,264	155.09
(OAI or "official action indicated") AND <facility name> AND (<Drug Name> OR (<Solvents> AND NOT <other drug names>))	3,241	14.27
("voluntary action indicated") AND <facility name> AND (<Drug Name> OR (<Solvents> AND NOT <other drug names>))	374	0.90
*diethylamine or "**diethyl amine"	33,436	117.05
*dimethylamine or "**dimethyl amine"	41,618	81.72
*dimethylformamide	41,261	96.33
*dimethylmethanamide	37	0.23
ghost	7,475	11.61
NDEA	69,935	226.70
NDMA	80,542	269.98
nitra	73,475	176.48
nitrite	51,400	120.44
nitrosa	59,164	196.53
nitroso	52,097	134.84
NMBA (deferred to after JPML decision)	10,340	17.13
trosomine	0	0.00
((Form483) or (Form /3 483) or (483 /3 letter) or (483 /3 warn*) or (704 pre/3 b)) AND <facility name> AND (<Drug Name> OR (<Solvents> AND NOT <other drug names>))	10,289	23.63
C2H6N2O or "(CH3)2NN=O" or "CH32NN=O" or "(CH3)2NC(O)H" or CH32NCOH or C3H7NO or "(CH3CH2)2NH" or CH3CH22NH or C4H11N or "(CH3)2NH" or CH32NH or C2H7N or "(C2H5)2NNO" or C2H52NNO or C4H10N2O	607	3.93
carcin* AND (<Drug Name> OR (<Solvents> AND NOT <other drug names>))	58,960	144.91
deviat* /5 cancer* or deviat* /5 toxic or or deviat* /5 hazard* or deviat* /5 fatal	430	1.09
(FDA /10 warning) AND <facility name> AND (<Drug Name> OR (<Solvents> AND NOT <other drug names>))	15,180	172.98
gene* /3 mutat*	18,649	33.79
genotoxic* AND (<Drug Name> OR (<Solvents> AND NOT <other drug names>))	83,605	207.48
solvent /5 cancer* or solvent /5 toxic or or solvent /5 hazard* or solvent /5 fatal	3,883	11.79
solvent* /5 contamin*	14,214	25.17

(test* /5 canc*) AND (<Drug Name> OR <Solvents> AND NOT <other drug names>))	9,632	22.36
Valisure*	1,704	5.52

	Hits	Gigabytes
("adverse event*" or AER) /50 (<drug name> /50 (<medical conditions>	773	0.75
"prior approval supplement" /50 (<drug name> OR (*78020* OR *90866* OR *90483*))	633	0.47
adulterat* /50 (<drug name> OR <solvents> OR <facility names>)	740	0.94
alert* /50 (<drug name> OR <solvents> OR <facility names>)	68,166	212.93
Citizen* pre/3 Petition /50 (<drug name> OR <solvents> OR <facility names>)	4,752	10.22
import* /3 (ban or alert or restrict*) /50 (<drug name> OR <solvents>)	4,484	60.49
inadequat* /50 (<drug name> OR <solvents> OR <facility names>)	18,212	36.23
inspect* /50 <drug name>	51,954	157.43
investigat* /50 <drug name>	111,434	332.94
major /3 change /50 (<drug name> OR <solvents> OR (*78020* OR *90866* OR *90483*))	4,372	10.47
minor /3 change /50 (<drug name> OR <solvents> OR (*78020* OR *90866* OR *90483*))	6,024	32.81
moderate /3 change /50 (<drug name> OR <solvents> OR (*78020* OR *90866* OR *90483*))	69	0.12
Monthly /3 update /50 (<drug name> or <solvents>)	430	0.33
(official pre/3 action* /4 indicat*) /50 (<drug name> OR <solvents> OR <facility names>)	219	1.00
observation* /50 (<drug name> OR <facility name>)	133,771	381.93
(OOS or "out of spec*" or "out-of-spec*") /50 (<drug name> OR <solvents> OR <facility names>)	325,512	627.58
(OOT or "out-of-trend" or "out of trend") /50 (<drug name> OR <solvents> OR <facility names>)	128,512	239.24
PADER* /50 (<drug name> OR <solvents> OR <facility names>)	1,305	1.24
(VAI or (voluntary pre/3 action* /4 indicat*)) /50 (<drug name> OR <solvents> OR <facility names>)	7,197	97.52
violat* /50 (<drug name> OR <solvents> OR <facility names>)	8,634	41.70

NOTES:

REMOVED:

"changes being effected"

CFR or eCFR or "code of federal regulations" or USC or "United States Code" or "Title 21"

(Establishment pre/3 Inspection)

warn*

(master /3 file) /50 (<drug name> OR <solvents>)

MOVED:

CAPA or corrective pre/3 "preventive action" to QA-Testing tab

	Hits	Gigabytes
((bottle pre/2 lies) or Eban) /50 ("inspect*" OR "FDA" OR "Food /50 Drug Administration" OR FDA OR USFDA OR "US-FDA" OR "Agency" OR "recall" OR <medical conditions> OR <drug name> OR <solvents> OR test OR chromatog* OR peak)	489	0.40
(bury OR burie* OR conceal*) /50 ("inspect*" OR "FDA" OR "Food /50 Drug Administration" OR FDA OR USFDA OR "US-FDA" OR "Agency" OR "recall" OR <medical conditions> OR <drug name> OR <solvents> OR test OR chromatog* OR peak)	4,070	9.19
(cGMP* or (current pre/5 manufacturing) or GMP*) /50 (<drug name> OR <solvents> OR inspect* OR violat*)	319,273	693.10
("cover up*" or coverup* or "cover-up*") /50 ("inspect*" OR "FDA" OR "Food /50 Drug Administration" OR FDA OR USFDA OR "US-FDA" OR "Agency" OR "recall" OR <medical conditions> OR <drug name> OR <solvents> OR test OR chromatog* OR peak)	635	1.16
(crash* or disaster*) /50 (<drug name> OR <solvents> OR "backup /3 data" OR "test")	5,640	14.62
(data /4 integrity or data /4 reliabl*) /50 (<drug name> OR <solvents> OR "backup /3 data" OR "test" or chromatog*)	33,744	88.84
(destroy* NOT "immediately destroy all electronic") /50 (<drug name> OR <solvents> OR facilities names OR test OR chromatog* OR backup /3 data)	32,795	101.82
delet* /50 (<drug name> OR <solvents> OR facilities names OR test OR chromatog* OR backup /3 data)	201,855	266.35
destroy* /50 (<drug name> OR <solvents> OR facilities names OR test OR chromatog* OR backup /3 data)	47,209	127.38
trash* /50 (<drug name> OR <solvents> OR facilities names OR test OR chromatog* OR backup /3 data)	1,210	4.41
shred* /50 (<drug name> OR <solvents> OR facilities names OR test OR chromatog* OR backup /3 data)	6,243	22.79
(hide* OR suppress*) /50 ("inspect*" OR "FDA" OR "Food /50 Drug Administration" OR FDA OR USFDA OR "US-FDA" OR "Agency" OR "recall" OR <medical conditions> OR <drug name> OR <solvents> OR test OR chromatog* OR peak)	87,076	84.07
whistleblow* /50 ("inspect*" OR "FDA" OR "Food /50 Drug Administration" OR FDA OR USFDA OR "US-FDA" OR "Agency" OR "recall" OR <medical conditions> OR <drug name> OR <solvents> OR test OR chromatog* OR peak)	2,504	1.82

NOTES:

Removed:

remov*

	Hits	Gigabytes
("anion-exchange" OR anionexchange OR "anion exchange") /50 (<drug name> OR <solvents>)	1,003	2.52
("ion-exchange" OR ionexchange OR "ion exchange") /50 (<drug name> OR <solvents>)	1,838	5.42
PCRC /50 (<drug name> OR <solvents>)	76	0.57
ALS /50 (<drug name> OR <solvents>)	2,285	7.31
bioequiv* /50 (<drug name> OR <solvents>)	17,221	26.12
(CAPA or corrective pre/3 "preventive action") /50 <facility name> /50 (<drug name> OR <solvents> OR QA OR "quality assurance" OR QC OR "quality control" OR Chromato* OR aberran /3 peak* OR abnorm* OR complain* OR "unknown /3 peak" OR "unknown /3 spike" OR "unknown /3 impurit*" OR "unknown /3 contamin*")	82,069	304.06
Chromato* /50 (<drug name> OR <solvents> OR aberran /3 peak* OR abnorm* OR complain* OR "unknown /3 peak" OR "unknown /3 spike" OR "unknown /3 impurit*" OR "unknown /3 contamin*")	191,390	501.35
contami* /50 (<drug name> OR <solvents> OR aberran /3 peak* OR abnorm* OR complain* OR "unknown /3 peak" OR "unknown /3 spike" OR "unknown /3 impurit*")	98,309	414.03
degradant* or impurit* /50 (<drug name> OR <solvents> OR aberran /3 peak* OR abnorm* OR complain* OR "unknown /3 peak" OR "unknown /3 spike" OR "unknown /3 impurit*" OR "unknown /3 contamin*")	513,437	1,020.00
detect* /50 (<drug name> OR <solvents> OR aberran /3 peak* OR abnorm* OR complain* OR "unknown /3 peak" OR "unknown /3 spike" OR "unknown /3 impurit*" OR "unknown /3 contamin*")	180,412	595.55
EL-MS or EL-MS or "electron ionization" /50 (<drug name> OR <solvents>)	17	0.02
elude* /50 (<drug name> OR <solvents> OR aberran /3 peak* OR abnorm* OR complain* OR "unknown /3 peak" OR "unknown /3 spike" OR "unknown /3 impurit*" OR "unknown /3 contamin*")	286	0.07
fatal* /50 (<drug name> OR <solvents>)	3,395	7.26
GC or "GC-FID" or GCMS or "GC-MS" /50 (<drug name> OR <solvents>)	145,607	286.75
hazard* /50 (<drug name> OR <solvents> OR aberran /3 peak* OR abnorm* OR complain* OR "unknown /3 peak" OR "unknown /3 spike" OR "unknown /3 impurit*" OR "unknown /3 contamin*")	26,688	143.63
heat /50 (<drug name> OR <solvents> OR aberran /3 peak* OR abnorm* OR complain* OR "unknown /3 peak" OR "unknown /3 spike" OR "unknown /3 impurit*" OR "unknown /3 contamin*")	49,940	121.79
HPLC-UV /50 (<drug name> OR <solvents>)	0	0.00
HS /50 (<drug name> OR <solvents>)	13,881	36.59
incomplet* /5 data* /50 (<drug name> OR <solvents> OR facilities names OR test OR chromatog* OR peak)	10,686	38.72
LCMS (<drug name> OR <solvents>)	13,514	16.24
mass spectro* /50 (<drug name> OR <solvents> OR aberran /3 peak* OR abnorm* OR complain* OR "unknown /3 peak" OR "unknown /3 spike" OR "unknown /3 impurit*" OR "unknown /3 contamin*")	7,746	27.41
"method /5 qualification" /50 (<drug name> OR <solvents>)	1,502	2.15
noise* /50 (<drug name> OR <solvents> OR aberran /3 peak* OR abnorm* OR complain* OR "unknown /3 peak" OR "unknown /3 spike" OR "unknown /3 impurit*" OR "unknown /3 contamin*")	18,527	42.78
"noti* w/5 pharm*" /50 (<drug name> OR <solvents>)	5,532	4.57
obscure* /50 (<drug name> OR <solvents> OR aberran /3 peak* OR abnorm* OR complain* OR "unknown /3 peak" OR "unknown /3 spike" OR "unknown /3 impurit*" OR "unknown /3 contamin*")	740	2.16
"press /4 release" /50 (<drug name> OR <solvents>)	6,627	48.28
"preventative /5 action" /50 (<drug name> OR <solvents>)	1,025	1.71
puri* /50 (<drug name> OR <solvents> OR aberran /3 peak* OR abnorm* OR complain* OR "unknown /3 peak" OR "unknown /3 spike" OR "unknown /3 impurit*" OR "unknown /3 contamin*")	226,078	554.80
recall* /50 <drug name>	39,471	252.16
"repe* /4 error*" /50 (<drug name> OR <solvents> OR aberran /3 peak* OR abnorm* OR complain* OR "unknown /3 peak" OR "unknown /3 spike" OR "unknown /3 impurit*" OR "unknown /3 contamin*")	1,125	4.31

residu* /50 (<drug name> OR <solvents> OR aberran /3 peak* OR abnorm* OR complain* OR "unknown /3 peak" OR "unknown /3 spike" OR "unknown /3 impurit*" OR "unknown /3 contamin*")	199,202	566.57
retrospec* /50 (<drug name> OR <solvents>)	6,054	12.28
risk* /50 (<drug name> OR <solvents> OR aberran /3 peak* OR abnorm* OR complain* OR "unknown /3 peak" OR "unknown /3 spike" OR "unknown /3 impurit*" OR "unknown /3 contamin*")	210,727	664.78
signal* /50 (<drug name> OR <solvents> OR aberran /3 peak* OR abnorm* OR complain* OR "unknown /3 peak" OR "unknown /3 impurit*" OR "unknown /3 contamin*")	20,007	54.34
spectro* /50 (<drug name> OR <solvents> OR aberran /3 peak* OR abnorm* OR complain* OR "unknown /3 peak" OR "unknown /3 impurit*" OR "unknown /3 contamin*")	40,174	236.21
spike* /50 (<drug name> OR <solvents> OR aberran /3 peak* OR abnorm* OR complain* OR "unknown /3 peak" OR "unknown /3 impurit*" OR "unknown /3 contamin*")	25,380	84.60
suitab* /50 (<drug name> OR <solvents> OR aberran /3 peak* OR abnorm* OR complain* OR "unknown /3 peak" OR "unknown /3 impurit*" OR "unknown /3 contamin*")	134,529	387.07
toxic* /50 (<drug name> OR <solvents> OR aberran /3 peak* OR abnorm* OR complain* OR "unknown /3 peak" OR "unknown /3 impurit*" OR "unknown /3 contamin*")	44,403	155.75

NOTES:

REMOVED:

fail*

observation

problem

quality

headspace

unknown* or unk or unks

validat*

aberran* /50 abnorm* /50 complain* /50 peak* used as modifiers rather than search terms

	Hits	Gigabytes
"PROCESS I" or "PROCESS II"	5,821	26.29
assay*	194,227	535.75
assessment*	128,558	448.50
batch /5 records	24,068	65.07
biocompat*	786	2.01
byproduct*	4,098	8.83
certificat*	63,350	176.71
change* /3 control*	73,130	194.17
change* /5 process*	56,936	166.85
COA or certificat* pre/3 analys*	133,379	330.26
concentra*	88,002	296.94
condensa*	12,937	31.59
conversion*	24,023	94.85
critical /4 change	543	0.59
crude*	54,381	101.16
deviat*	60,059	176.50
diastereo*	5,068	13.34
discrepanc*	17,587	25.95
esterficat*	26	0.03
formaldehyde	42,000	84.00
malfunc*	5,964	15.12
material* /3 loss*	1,404	2.37
moiety or moieties	6,097	22.14
process /5 change	41,199	143.67
quench*	11,222	25.55
reagent*	76,034	200.59
reclaim*	146	0.16
recover*	139,542	377.30
recycl* /2 solvent AND <drug name>	1,026	669.56
repack* or "re-pack"	12,829	131.06
resal*	120	1.05
resell*	72	0.57
reuse*	4,601	8.49
ring*	19,039	66.54
suppress*	3,538	9.56
TEA or Triethyl*	232,891	395.20
temperature	122,825	306.32
TIN or Tributyl*	102,102	274.95
yield*	107,458	258.39

**<Term> /50 (<Drug
Name> OR
(<Solvents> AND NOT
<other drug names>))**

NOTES:

Removed:

error*

expir*

solvent*

Moved:

CAPA or corrective pre/3 "preventive action" to

QA-Testing tab

	Hits	Gigabytes
bladder*	2,013	4.84
cancer* or precancer* or pre-cancer*	18,558	25.98
colon*	3,810	10.52
death* or dead or fatal	9,588	33.05
esophag*	1,033	2.02
gastro*	13,874	42.66
intestin*	3,552	9.14
kidn* or renal*	8,936	22.22
laten*	435	1.00
leukemia*	2,663	7.17
liver*	7,627	17.68
lymphoma*	2,793	9.66
muta*	11,286	26.72
myeloma*	738	2.25
NHL or non-hodgkin*	703	1.51
toxicolog*	14,342	72.88
onset*	4,457	13.53
oncolog*	7,244	13.93
ovar*	2,510	6.13
pancrea*	5,236	12.16
prostate*	1,502	3.61
stomach*	3,958	9.12

NOTES:

Removed:

blood*

<Term> /50 (<Drug
Name> OR (<Solvents>
AND NOT <other drug
names>))

	Hits	Gigabytes
Alembic	20,176	83.89
ABDC or Amerisource* or "American Health Packaging" or AHP	33,542	65.58
Amerigen	1,596	4.04
ANDA /3 Inc*	23,300	84.28
Auro* or APL or APUSA	106,913	418.46
boehringer ingelheim	27,301	67.32
Bristol	34,387	86.59
Camber	3,519	8.38
Cobalt	16,198	47.01
Forest	19,874	96.24
Hetero	61,501	271.60
Huahai	40,432	138.15
Indoco	4,318	20.33
Ivax	5,564	12.38
Jubilant	37,872	74.63
Lantech*	26,910	46.88
Macleod*	10,622	36.41
Novartis	68,256	213.80
Par	61,255	238.45
Prinston	1,777	2.41
Qualanex	39	0.10
Ranbaxy	39,513	72.14
Sandoz	86,690	404.67
Syncore	182	0.22
Synthon	22,884	195.29
Teva	171,183	526.46
Torrent	74,777	219.07
Unichem	51,211	198.26
Watson	30,491	76.18
Zhejiang*	89,398	313.60
ZHP	689	1.47

**<Term> AND (<Drug Name>
OR (<Solvents> AND NOT**